contamination of equipment, reagents, and/or supplies.

• RNA work areas must be separated from DNA work areas.

Specimen Integrity

• Requirements to ensure identification of the subject being testing include: date of birth; gender; ethnicity; patient or family number; specimen source; time of collection; and name of person obtaining sample

Validation of Tests

Analytic validation:

• Laboratories must verify or establish reproducibility for each method within and between runs, and between technologists.

• Methodology must be appropriate for conditions being evaluated.

• Quality control parameters must be applicable.

• Reagents must be validated.

Clinical Validation: Laboratories must consider the following clinical parameters for test validation:

• A positive confirmatory test must have a defined positive predictive value which can be communicated to the care giver.

• Where the disease prevalence is more frequent than 1/10,000, the validity must be documented in at least 10 positive probands (including cell lines or DNA/RNA) prior to offering the test.

• Predictive value should be defined in terms of ethnic populations, when applicable

C. *Issue:* These recommendations are based on what the CLIAC considers to be good laboratory practice in genetic testing. They represent extensions to existing requirements to specifically address some of the unique aspects of genetic testing. Are these sufficiently comprehensive, adequate, or are they not needed?

Proficiency Testing (PT)

A. *Current CLIA Requirement:* Under 493.801 Condition; Enrollment and testing of samples—a laboratory must enroll in an approved proficiency testing program for each specialty for which it seeks certification. Currently, no PT requirement exists, because there is no genetic specialty, therefore the following PT requirement applies. Under 493.1703 Standard; Comparison of test results—when a laboratory performs tests for which PT is unavailable, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year.

B. *CLIAC Recommendation:* The CLIAC recommended including the following new provision:

• When an approved PT program does not exist for the test, the regulations should require alternatives (to be performed three times per year, on five specimens per event). Examples include: Split samples sent to another laboratory; blinded test samples; test samples in duplicate by separate technologists, in a blinded manner; and other equivalent approaches

C. *Issue:* Requiring PT would provide a basis for evaluating the accuracy of genetic testing.

Post-Analytic Phase

Special Reporting Requirements

A. *Current CLIA Requirement:* Under 493.1109 Standard; Test report—a laboratory must, upon request, make available to clients a list of test methods and information that may affect the interpretation of test results, such as interferences.

B. *CLIAC Recommendation:* Laboratory reports must include the following, as applicable, as they relate to the interpretation of the test result:

—Interpretation.

—Comments.

—Recommendations for further testing or clinical consultation.

—Summary of the test method and its limitations.

• When individual interpretation of the test result is required, the signature of the Director or designee must appear on the report.

• A means to quickly contact the Laboratory Director/Technical Supervisor, in addition to address, must be indicated on the report.

• Any reference to family members in a test report must utilize standardized pedigree nomenclature or numeric indicators, instead of individual names.

• Specific requirements for reporting molecular genetic testing include:

—A list of the mutant alleles tested.

—The rate detection of the panel.

— A revised assessment of likelihood based on test results, as applicable.

—Important clinical implications for other family members should be provided, as applicable.

—Variables that affect test interpretation (*e.g.* ethnicity) must be specified in the report, and limitations of the testing must be defined.

C. *Issue:* Requiring laboratories to provide this information could increase the accuracy of interpretation of genetic testing reports, but may increase the laboratories' burden.

Record/Specimen Retention

A. *Current CLIA Requirement:* Under 493.1109 Standard; Test report—the laboratory must retain the original or an exact duplicate of each test report for a period of at least two years after the date of reporting.

B. *CLIAC Recommendation:*

• Copies of patient reports of genetic testing shall be retrievable for a minimum of 10 years, or longer if required by State law. Electronic reports are acceptable.

• The laboratory must have a policy defining specimen retention policies.

C. *Issue:* Maintaining reports for a longer period of time may be beneficial but this could be burdensome.

Dated: April 27, 2000.

Jeffrey Koplan,

Director, Centers for Disease Control and Prevention.

[FR Doc. 00–11093 Filed 5–3–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00107]

Population-Based Surveillance of Autism Spectrum Disorders and Other Developmental Disabilities; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Population-Based Surveillance of Autism Spectrum Disorders and other Developmental Disabilities. CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010.'' This announcement is related to the focus area of Maternal, Infant and Child Health. http://www.health.gov/healthypeople.

The purpose of the program is to: Enhance an existing system or develop and implement a new system to undertake a multiple source surveillance methodology, from existing data records, for determining the prevalence of autism and other developmental disabilities, such as mental retardation, cerebral palsy, and vision and hearing impairments, in 3–10 year-old children within a geographically-defined area (combination of States, Statewide, or regions within a State).

B. Eligible Applicants

Assistance will be provided only to the health departments of States or their

bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Applicants must document a surveillance population of at least 30,000 live per births per year within a State, area of a state (such as the catchment of a local health agency), or a combination of States.

Note: Only one application will be accepted from each State or combination of States, and the latter must specify which State is the lead applicant.

C. Availability of Funds

Approximately $300,000 is available in FY 2000 to fund two awards. Each award is expected to be approximately $150,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. To develop or enhance a surveillance program for autism and other developmental disabilities:

i. Develop surveillance case definition(s);

ii. Develop multiple source surveillance methodology; and

iii. Develop data collection instruments and methods for obtaining information from medical/clinical and school records.

b. Establish a multiple-source methodology to ascertain cases of autism and generate population-based prevalence estimates by developing collaborative relationships with appropriate professionals and organizations.

c. Develop a plan for training community service providers to improve case ascertainment.

d. Implement quality assurance procedures, including clinical validation of diagnoses in a sample of cases, to ensure that study protocols are being followed.

e. Develop an evaluation plan for estimating the completeness of the surveillance system.

f. Compile and disseminate the findings of the project.

2. CDC Activities

a. Assist recipient in the development and implementation of surveillance activities including the development of a standardized surveillance case definition.

b. Provide current scientific information on surveillance methods.

c. Provide assistance in the development of an evaluation plan for the completeness of the surveillance system.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 double-spaced pages, printed on one side, with one inch margins, unreduced font, unbound, and unstapled.

F. Submission and Deadline

Application

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are in the application kit.

On or before July 7, 2000, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the Objective Review Panel. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Understanding of the Problem (20 Percent)

(a) The extent to which the applicant has a clear, concise understanding of the requirements, objectives, and purposes of the cooperative agreement.

(b) The extent to which the application reflects an understanding of the complexities of autism and developmental disabilities surveillance.

2. Technical Approach (30 Percent)

The extent to which the applicant describes the planning process, including specific planning objectives, strategies for achieving these objectives, and describes an approach to surveillance of autism and other developmental disabilities. The applicant should demonstrate its collaboration with health and education services that would be appropriate sources of cases for the surveillance system (by letters of support). The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

3. Capability and Experience (30 Percent)

The extent to which the applicant has the professed skills and experience to conduct a project of this nature, including reputation in the field and demonstrated experience in conducting similar projects.

4. Staffing and Management Resources (20 Percent)

The extent to which the applicant demonstrates that the proposed Project Director or Principal Investigator is knowledgeable regarding autism, developmental disabilities, and surveillance issues, as evidenced by publications, presentations, or other materials that document prior work. The extent to which the applicant demonstrates that other project staff

have appropriate training and experience in the field of autism, other developmental disabilities, and surveillance activities, as evidenced by publications, presentations, or other materials that document prior work. Demonstration of the ability to provide adequate facilities and other necessary resources to carry out all proposed activities.

5. Budget (Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the stated objectives and proposed activities.

6. Human Subjects Requirements (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services regulation (45 CFR part 46) on the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual reports, no more than 30 days after the end of the report period;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. sections 241 and 247b, as amended]. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other documents may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov (click on funding).

Please refer to Program Announcement 00107 when you request information. For business management technical assistance, please contact: Mattie B. Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770/488–2718, Email address: mij3@cdc.gov.

For program technical assistance, contact: Tom Horne, Principal Management Officer, Developmental Disabilities Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (F–15), 4770 Buford Hwy, NE, Atlanta, GA 30341, Telephone: 770/488–7364, Email address: tjh1@cdc.gov.

Dated: April 28, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–11092 Filed 5–3–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00103]

C. Everett Koop Community Health Information Center—A National Model for Physician-Based Community Health Information Centers; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a grant program entitled ''C. Everett Koop Community Health Information Center—A National Model for Physician-based Community Health Information Centers.''

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010'' a national activity to reduce morbidity and mortality and improve the quality of life. This program addresses the ''Healthy People 2010'' focus area of Health Communication.

For the conference copy of ''Healthy People 2010,'' visit the internet site: http://www.health.gov/healthypeople.

The purpose of the program is to strengthen the C. Everett Koop Community Health Information Center (CHIC) by (1) conducting a follow-up evaluation of CHIC as an effective model for other community health information centers, (2) disseminating the results of the evaluation to professional medical societies nationwide, and (3) conducting a final assessment of the dissemination and use of the model in other communities.

B. Eligible Applicants

Assistance will be provided only to the C. Everett Koop Community Health Information Center, Philadelphia College of Physicians, Philadelphia, PA. No other applications are solicited. The sole source justification is based on congressional language in fiscal year 2000 CDC Appropriation, which provides earmarked funding for the C. Everett Koop Community Health Information Center in Philadelphia, PA.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract loan, or any other form.

C. Availability of Funds

Approximately $200,000 is available in FY 2000 to fund the C. Everett Koop Community Health Information Center. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the following:

1. Strengthening the CHIC program by fully implementing the recommendations of the 1999 evaluation related to (a) marketing, promotion, and visibility, (b) resources, and (c) accessibility (See attachment I for recommendations).

2. Encouraging community involvement by developing a network of partners in providing current, complete, and comprehensive health information, and in increasing awareness of the availability of information resources.

3. After the recommendations have been fully implemented, developing a